UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TENNESSEE
AT GREENEVILLE

UNITED STATES OF AMERICA	)	
	)	
	)	
v.	)	No. 2:18–CR–140
	)	
	)	
PETER BOLOS	)	

MEMORANDUM OPINION AND ORDER

This matter is before the Court on Defendant Bolos's Motion for Judgment of Acquittal Pursuant to Rule 29 or in the Alternative Motion for New Trial Pursuant to Rule 33. [Doc. 702]. The United States filed a response in opposition, [Doc. 726], and Defendant Bolos replied, [Doc. 732]. For the reasons stated below, Defendant Bolos's Motion for Judgment of Acquittal Pursuant to Rule 29 or in the Alternative Motion for New Trial Pursuant to Rule 33, [Doc. 702], is DENIED.

I. Background

Before addressing the facts of this case, the Court needs to review pharmacy-benefits terminology. Starting with "Pharmacy benefit managers (PBMs)," PBMs are for-profit administrators that adjudicate prescription claims on behalf of insurance plans and reimburse pharmacies for dispensed drugs. [Doc. 278, PageID 4045, 4053].[1] Two examples of PBMs are CVS Caremark and Express Scripts. [*Id.* at PageID 4045]. When PBMs adjudicate claims, they take two prices into account: (1) average wholesale prices (AWP) and (2) "usual and customary price." [*Id.* at PageID 4053]. When PBMs adjudicate claims and calculate reimbursement rates,

[1] With the exception of Defendant's intent and knowledge, the Parties agree on many of the facts in the case. Further, the Parties dispute what the FSI alleges. Therefore, the Court will cite to the FSI for undisputed background information and to discuss the actual allegations, but the FSI is not evidence and will not be considered when evaluating the sufficiency of the evidence.

"the amount the PBMs would pay for a given medication would not exceed the lesser of" the AWP or the usual and customary price. [*Id.*].

What are "AWPs" and "usual and customary prices"? AWPs are the prices "reported by the manufacturer of that medication to data repository companies . . . . " [*Id.*]. And the "usual and customary prices" are prices that a customer would pay the pharmacy if the customer did not have insurance (the cash price). [*Id.*].

Turning to the particular facts of this case, on December 1, 2020, a grand jury returned a first superseding indictment ("FSI") charging Defendants Peter Bolos, Andrew Assad, Michael Palso, and others with conspiracy to commit health care fraud, 18 U.S.C. § 1349, mail fraud, 18 U.S.C. § 1341, and violations of the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 331(a), 353(b)(1), and 333(a)(2). [*See generally* Doc. 278]. Defendants Peter Bolos, Andrew Assad, and Michael Palso ("Synergy Principals") co-owned two pharmacies—Synergy Pharmacy Services Inc. ("Synergy") and Precision Pharmacy Management LLC ("Precision"). [*Id.* at PageID 4038–39].

The FSI alleges that Synergy and Precision entered into agreements with HealthRight LLC ("HealthRight"). [Doc. 278, PageID 4051–52]. During the conspiracy, "HealthRight purported to be a telemedicine company." [*Id.* at PageID 4043]. While the Government and Defendant Bolos dispute the contours of these agreements, such as how payments were calculated, the Parties do not dispute that HealthRight sent customers to Synergy and Precision if the customers had (1) private insurance and (2) prescriptions for particular medications. [Tr. of Derek Thibeau, Doc. 711, 267:12–268:20]. Prescriptions for medications, like lidocaine ointment, were filled by the pharmacies. [Tr. of Andrew Assad, Doc. 713, 83–85]. Synergy and Precision were then reimbursed by PBMs. [*Id.*].

The particular medications were selected based on profitability. [Tr. of Andrew Assad, Doc. 712, 258]. Keeping lidocaine ointment as the example, the FSI alleges that it was purchased at $27 per unit while the AWP was $381. [Doc. 278, PageID 4053]. At trial, Andrew Assad said that seven jars of lidocaine ointment would cost Synergy about $210, and the reimbursement rate (which is different than an AWP) for those seven jars would be in the ballpark of $3,000. [Doc. 713, 82:23–84:19].

As stated above, the AWPs are not set by pharmacies; manufacturers set the AWP. The Parties agree that no evidence at trial suggests that Defendant Bolos or the other Synergy Principals changed, raised, or manipulated the AWP. The Parties disagree about whether the FSI alleges that the Synergy Principals manipulated the AWP of medications. The source of this disagreement is a phrase used throughout the FSI, "Inflated AWP Medication." [*See generally* Doc. 278].

Based on the FSI, the phrase "Inflated AWP Medication" means "products at prices substantially below the manufacturer reported average wholesale prices ('AWP') of those medications . . . . " [*Id.* at PageID 4052]. The FSI alleges that the Synergy Principals knew that the PBMs would base the reimbursement rate on the *inflated*, as in *high*, AWP compared to how much the Synergy Principals paid for the medication. [*Id.* at PageID 4052–53]. Specifically, the FSI alleges that the Synergy Principals "knew that obtaining prescriptions for Inflated AWP Medications would make the conspiracy tremendously profitable because they understood how the PBMs' reimbursement methodology functioned." [*Id.* at PageID 4053]. While the FSI alleges that the Synergy Principals understood PBM reimbursement policies and sold products with high AWPs, the FSI contains no allegations that the Synergy Principals manipulated the pricing of the medications.

The phrase "Inflated AWP Medication" has been the subject of numerous filings and orders in this case. [*See, e.g.,* Doc. 133, 175]. Each time, the Government has reiterated that the Inflated AWP Medications served as the profit of the conspiracy, not the illegal act itself by price fixing. [Doc. 111, PageID 1103; Doc. 145, PageID 1486–87]. The term is at issue again in this motion.

Ultimately, Defendant Bolos went to trial, and a jury found Defendant Bolos guilty of one count of conspiracy to commit health care fraud, twenty-two counts of mail fraud, and one count of felony misbranding under the Food, Drug, and Cosmetic Act. [Doc. 663]. After the trial, he filed this Motion for Judgment of Acquittal Pursuant to Rule 29 or in the Alternative Motion for New Trial Pursuant to Rule 33. [Doc. 702].

II. Standards

Although one motion is before the Court, Defendant has requested two forms of alternative relief, each governed by its own standard. First, Defendant moved the Court for a judgment of acquittal under Federal Rule of Criminal Procedure 29. [Doc. 702, PageID 8553]. Judgments of acquittal are proper when "the government's proofs are legally insufficient to sustain a conviction." *United States v. Paulus*, 894 F.3d 267, 274 (6th Cir. 2018). The evidence is viewed "in the light most favorable to the prosecution . . . . " *Id.* (quoting *United States v. Persaud*, 866 F.3d 371, 380 (6th Cir. 2017)). An acquittal should not be entered "if '*any* rational trier of fact could have found the essential elements of the crime beyond a reasonable doubt.'" *Id.* (quoting *Persaud*, 866 F.3d at 380 (emphasis in original)). When ruling on a Rule 29 motion, courts do not weigh the evidence or judge witness credibility. *Id.* at 275. Additionally, circumstantial evidence adequately supports a guilty verdict, and "evidence need *not* remove every reasonable hypothesis except that of guilt." *United States v. Hughes*, 505 F.3d 578, 592 (6th Cir. 2007) (quoting *United States v. Stone,* 748 F.2d 361, 362 (6th Cir. 1984)). The ultimate inquiry is "whether a rational trier

of fact could return a guilty verdict." *Paulus*, 894 F.3d at 275 (citing *United States v. Fisher*, 648 F.3d 442, 450 (6th Cir. 2011)). This "standard is a great obstacle to overcome" for a defendant, and it is "a very heavy burden." *Hughes*, 505 F.3d at 592.

Second, Defendant Bolos's moves the Court, in the alternative, for a new trial pursuant to Rule 33 of the Federal Rules of Criminal Procedure. New trials are appropriate "only 'in the extraordinary circumstance where the evidence preponderates heavily against the verdict.'" *Hughes*, 505 F.3d at 592–93 (quoting *United States v. Turner,* 490 F. Supp. 583, 593 (E.D. Mich. 1979), *aff'd,* 633 F.2d 219 (6th Cir. 1980)). Under a Rule 33 motion, a district judge may assess witness credibility and consider the weight of evidence. *Id.* at 593. Additionally, a new trial should be granted when the interests of justice require it, such as, when a "substantial legal error has occurred." *United States v. Munoz*, 605 F.3d 359, 373 (6th Cir. 2010).

III. Select Evidence from Trial

In its response to Defendant Bolos's motion, the Government relies on a small fraction of the evidence heard by the jury to support the verdict. In its response, the Government prominently relies on the testimony of Pamela Guertin. Pamela Guertin was the Senior Inside Sales Representative at Synergy and managed the relationship with HealthRight. [Tr. Pamela Guertin, Doc. 630, 5:13–19]. She testified, in part, to the following:

- After receiving an adverse decision from a PBM, Synergy appealed. During the appeal process, Defendant or his co-conspirators instructed her to provide misrepresentations to PBMs regarding the relationship with HealthRight. [Tr. Pamela Guertin, Doc. 631, 90:20–25, 91–93].

- When testifying regarding the written agreements with HealthRight, she stated that Defendant and co-conspirators knew that "that they could not put the, like price they wanted per patient or prescription in the contract, and there were several times where I was asked to pull information about billed prescriptions and try to work a number backwards to get to how many [full-time equivalents] that Synergy needed." [Doc. 630, 27:25, 28:1–5]. After

the full-time equivalent formulation was abandoned, "Synergy would pay HealthRight $500 per intake." [*Id.* at 46:11].

- Defendant reviewed HealthRight's call scripts with the aim of soliciting particular answers for Synergy and omitting language about informing patients of their co-pays before shipping prescriptions. [*Id.* at 52–53:10, 130–131:18].

- When gathering doctor-attestations, Defendant received an email stating that "HealthRight d[id] not take part in the practice of medicine and, therefore, d[id] not independently verify anything the doctor is attesting to by signing this agreement." [Doc. 631, 6:12–7:11; Govt. Ex. 61N]. Further, Defendant received an email stating that the attestations needed to be altered to avoid raising "red flags" with PBMs. [Doc. 631, 9:8–11; Govt. Ex. 61M].

- Defendant did not take steps to ensure patients spoke with doctors, the Synergy Principals did not, to Ms. Guertin's knowledge, take any steps to verify if a physician-patient relationship existed, and a common customer complaint was that customers did "not know[] who the physician was or where the prescription came from." [Doc. 630, 141:20–25, 157:8–11, 181:18–23].

- If a lack of physician-patient relationship came up during an audit, the PBMs would recoup the money paid for that prescription. [*Id.* at 155:5–8].

- Doctors did not know which prescriptions patients actually received. [*Id.* at 86:4–11].

The Government also relies on testimony from two other people involved with Synergy. First, Andrew Assad testified that he told CVS Caremark that Synergy did not waive co-pays, but Synergy did waive co-pays. [Doc. 714, 19:14–20:2]. And second, Maikel Bolos, a purported pharmacist-in-charge at Synergy, testified that documents submitted to the State of Tennessee for a pharmacy license were false. [Doc. 711, 67:19–69:19].

Additionally, the Government discusses the testimony of PBM employees. The Government called Steve McCall, Vice-President of Network Service and formerly Director of Pharmacy Performance for CVS Caremark. [Tr. Steve McCall, Doc. 719, 24:11–25:8]. He testified to the following:

- He expressed his understanding of materiality, which was "in layman's terms, would we care, would [CVS] Caremark consider that it's an important item that happens." [*Id.* at 52:24-25].

- From CVS Caremark's perspective, prescriptions written without a doctor meeting or speaking to a patient would have been written without a valid physician-patient relationship. This was material, and he went so far as to say that CVS Caremark would not pay for claims where patients received a prescription from a doctor who had never spoken with or communicated with the patient. [*Id.* at 54:24–55:22].

- Whether a doctor knows what medication was received by the patient was material to CVS Caremark. [*Id.* at 57:20–58:7].

- Buying prescriptions was material to CVS Caremark. [*Id.* at 58:14–20].

- Not collecting or waiving co-pays was material to CVS Caremark. CVS Caremark would recoup any claims with uncollected co-pays. [*Id.* at 61:10–62:22].

- A pharmacy funding its own co-pays was material to CVS Caremark as it is equivalent to waiving the co-pays. [*Id.* at 63:3–8].

- Hiding ownership of pharmacies was material to CVS Caremark. [*Id.* at 64:2–11].

- Obtaining a state pharmacy license with false information was material. Any claims paid by CVS Caremark for that state would be recouped. [*Id.* at 63:19–64:1].

- The submission of false documents was material to CVS Caremark. [*Id.* at 64:15–24].

Last, the Government relies on testimony from Blake Stockwell, Senior Manager of the Pharmacy Special Investigations Unit for Express Scripts. [Tr. Blake Stockwell, Doc. 624, 2:21–22]. He testified to the following:

- He described materiality as "something that would, I guess, give Express Scripts pause or potentially impact our decision to do something. So in this case the materiality here would be, is it something that's important to us . . . . " [Doc. 624, 34:6–12].

- Fraudulently obtaining state pharmacy licenses was material to Express Scripts. [*Id.* at 43:15-25].

- Prescriptions written without a doctor meeting or speaking to a patient was not a valid physician-patient relationship from Express Scripts' perspective. This was material and any claim associated with the practice "would be subject to recoupment . . . . " [*Id.* at 62:9–63:17].

- Whether a doctor knows what medication was received by the patient was material to Express Scripts. [*Id.* at 67:20–68:10].
- Submitting false documents was material to Express Scripts. [*Id*. at 68:11–15].
- Failure to collect co-pays was material to Express Scripts, and a failure to collect co-pays was subject to recoupment. [*Id.* at 69–74].
- Buying prescriptions was material to Express Scripts. [*Id.* at 55:15–57:11].

IV. Discussion

In light of the evidence above and the evidence at trial, Defendant Bolos has not met his burden for either an acquittal or for a new trial. A reasonable fact finder could have found that the evidence supported all elements of the offenses beyond a reasonable doubt, the evidence does not preponderate heavily against the verdict, and no substantial legal error has occurred. Therefore, his motion must be denied. The Court will address each of his arguments, beginning with his last argument and then addressing the first seven arguments.

a. The Government did not vary from the FSI when presenting its proof.

Addressing Defendant's last argument first, the proof at trial did not vary from the FSI. [Doc. 702, PageID 8584]. Defendant contends that the FSI alleges that he manipulated the AWPs for the drugs sold by Synergy and Precision. [*Id.* at PageID 8584–85]. He goes on to say that the proof at trial established that he did not manipulate prices, and in response, the United States changed the allegations and proof against him at trial, creating a variance. [*Id.* at PageID 8585].

A "variance" is created when, absent an amendment to the indictment, the government's proof at trial is "materially different from [that] alleged in the indictment." *United States v. Budd*, 496 F.3d 517, 521 (6th Cir. 2007) (quoting *United States v. Prince*, 214 F.3d 740, 756–57 (6th Cir. 2000)). Under some circumstances, a variance may entitle a defendant to relief. *Id.* at 255. To obtain relief, a defendant must satisfy a two-prong test: "(1) the variance must be demonstrated

and (2) the variance must affect some substantial right of the defendant." *Id.* (quoting *Prince*, 214 F.3d at 757). Defendant Bolos satisfies neither prong.

First, Defendant Bolos has not demonstrated a variance. While the FSI uses the term "Inflated Average Wholesale Price ('AWP') medication," the FSI never accused Defendant, or anyone involved with Synergy, with changing the AWP. The AWP abbreviation implies that the AWP for drugs was high while the purchase price was low. Nothing in the FSI indicates that members of the conspiracy changed the price of drugs. Further, the FSI includes the alleged criminal conduct of Defendant and his co-conspirators, and the Government produced evidence at trial consistent with the allegations. [Doc. 278, PageID 4051–69].

Second, even if a variance existed, Defendant would not be entitled to an acquittal or a new trial because he has not shown that a substantial right was affected. Defendant can show a substantial right was affected by "show[ing] prejudice to his ability to defend himself at trial, to the general fairness of the trial, or to the indictment's sufficiency to bar subsequent prosecutions." *United States v. Mize*, 814 F.3d 401, 409 (6th Cir. 2016) (quoting *U.S. v. Kuehne,* 547 F.3d 667, 683 (6th Cir. 2008)).

Defendant cites two cases when discussing substantial rights, neither of which establish that the Government varied from the FSI in this case. First, in *Epstein*, two defendants were charged with mail fraud. *Epstein v. United States*, 174 F.2d 754, 756 (6th Cir. 1949). The defendants were officers and directors of breweries. *Id.* The indictment alleged that the defendants were selling supplies to the companies for which they worked at excessive prices and above market price. *Id.* at 756–57. However, the evidence at trial showed that the defendants sold the supplies at or below market price. *Id.* at 761. In response to the evidence that the supplies were sold at or below market price, the government then argued that selling the supplies at any price where the

defendants received a profit was a breach of their fiduciary relationships and fraud. *Id.* at 760–62. While the *Epstein* court did not describe which substantial right was inhibited, it did say that good faith would be a defense to the new argument brought by the government. *Id.* at 763. Inferring that a new defense robbed the defendants of preparing such a defense, the defendants' ability to prepare for trial would have likely been mitigated. *See also id.*

The *Epstein* case is much different than Defendant Bolos's. While the government in the *Epstein* case actually changed its theory at trial, the Government did not change its theory here. In *Epstein*, evidence at trial contradicted the indictment, but in this case, the FSI does not include contrary information to that presented at trial. Further, Defendant Bolos's ability to prepare for trial was not inhibited. In fact, his counsel succinctly summarized their view that the FSI did not allege manipulating AWPs or other prices. After the Court used the term "inflated" when giving potential jurors a background of the case, Defendant's counsel explained, out of the presence of the jury, their understanding of the case. "[Y]ou buy low and reimburse high, and the defendants have nothing to do with setting that, that reimbursement rate . . . . " [Tr. for Nov. 1, 2021, 51:12–14]. Defense counsel reiterated that Defendant Bolos could not and did not set any reimbursement rates. [*Id.* at 53:7–11]. Additionally, the counsel for the Government made explicitly clear, "I don't want the jury to think that there's some price fixing going on here." [*Id.* at 48:11–13].

In sum, the *Epstein* case is distinguishable from Defendant's case. The Government did not change its theory of the case, and the defense was not surprised that price manipulation was not the Government's theory of the case.

The second case cited by Defendant is *United States v. Mize*, 814 F.3d 401 (6th Cir. 2016). In *Mize*, the Sixth Circuit recognized that "[t]he primary risk that the variance doctrine is designed to alleviate is guilt transference—'that the appellant was convicted based on evidence of a

conspiracy in which the appellant did not participate.'" *Id.* at 411. (quoting *United States v. Hughes*, 505 F.3d 578, 587 (6th Cir. 2007)). In that case, the government created a variance when it submitted substantial evidence involving two different conspiracies, but the defendant only participated in one of them. *Id.* at 412. The evidence introduced in the *Mize* case created a great risk of guilt transference and therefore supported a finding of a variance. *Id.*

Here, Defendant argues, "just as in *Mize*, and the cases above, the government changed its theory, and the Government has now convicted Dr. Bolos for the crimes of others." [Doc. 702, PageID 8588]. Defendant does not elaborate on his point, and *Mize* is inapplicable to his case. As discussed with *Epstein*, the Government did not change its theory of the case, and the Government did not introduce substantial evidence of a conspiracy that Defendant did not participate in. Defendant's argument that there is a risk of guilt transference is unpersuasive.

In conclusion, Defendant Bolos failed to establish a variance in this case. The Government's proof at trial did not contradict the FSI, and the FSI does not contain any allegations that Defendant Bolos or his co-conspirators manipulated AWPs or other prices. Additionally, Defendant Bolos has not shown a risk of guilt transference.

b. Defendants' Arguments One through Seven

Defendant's first seven arguments are not suited for the facts of this case and are quickly repudiated. Instead of discussing conspiracy to commit health care fraud, mail fraud, felony misbranding, or, frankly, the evidence in this case, Defendant attempts to change the conversation. His arguments focus on the False Claims Act, Anti-Kickback Statute, and points unsupported by the law that he cites as authority.

When examining Defendant's arguments in light of the elements of his convictions, it is difficult to see how any one of his arguments would overturn the verdicts. The United States goes

so far as to say that Defendant's motion appears "recycled from another case . . . . " [Doc. 726, PageID 11168]. While this Court will not make a similar statement, Defendant's arguments and conclusions do not flow from the facts of the case, applicable law, or even the procedural history of the case.

1. Implied False Certification Theory

Defendant argues that the convictions should be overturned because the Court should (1) analyze the facts of this case through the lens of the False Claims Act, 31 U.S.C. §§ 3729–3733, and the "implied false certification theory," (2) apply that analysis to conspiracy to commit health care fraud and mail fraud, and (3) then determine that the misrepresentations evidenced at trial were immaterial. For Defendant's argument to prevail, all three of those premises must be correct. All three are wrong.

First, this case should not be analyzed through the False Claims Act ("FCA"). The "implied false certification theory" is one form of liability under the FCA. *Universal Health Servs., Inc. v. United States ex rel. Escobar,* 579 U.S. 176, 180 (2016). An implied false certification involves a claim for repayment. *Id.* "[W]hen a defendant submits a claim, [he] impliedly certifies compliance with all conditions of payment" including compliance with any "material statutory, regulatory, or contractual requirement . . . . " *Id.* But by certifying compliance, any "material statutory, regulatory, or contractual" violation could be "a misrepresentation that renders the claim 'false or fraudulent' under" the FCA. *Id.*

Only certain implied false certifications will make a person liable under the FCA. *Id.* at 190. The misrepresentation must (1) be "specific representations about the goods or services provided" and (2) "the defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths." *Id.*

Material means "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." *Id.* at 192–93.

Defendant's case does not solely revolve around certifications stating that all laws and contracts had been followed. Instead, this case includes misrepresentations and omissions regarding failures to collect co-pays, waiving co-pays, self-funding co-pays, knowingly filling prescriptions without a physician-patient relationship, filling prescriptions by using a fraudulently obtained state license, audits, attestations, and more. Defendant does not explain how these allegations and the evidence at trial supporting them fit within the implied false certification theory of the FCA.

The second piece of Defendant's argument also fails. Defendant argues that the Court should apply the implied false certification theory and its definition of materiality to this case because the Sixth Circuit has done it in a similar case, *United States v. Bertram*, 900 F.3d 743 (6th Cir. 2018). [Doc. 702, PageID 8559]. Contrary to Defendant's argument, *Bertram* does not stand for that principle.

Bertram is a criminal case, not a civil FCA case. The criminal case had five defendants, all involved with the treatment of substance abuse as doctors or as owners of drug testing services. *United States v. Bertram*, 900 F.3d 743, 747 (6th Cir. 2018). The defendants started a urinalysis testing company "to run the tests ordered by physicians at drug treatment clinics . . . . " *Id.* at 747. "Physicians at the clinics ordered urinalysis tests to check if their patients used illicit drugs and to monitor their medications." *Id.* The defendants' new company, PremierTox, began receiving samples for tests that it could not perform. *Id.* When it finally got the equipment, the equipment malfunctioned. *Id.* Without the proper equipment, test samples created a backlog. *Id.* Some samples did not get tested or have results for ten months. *Id.* Even still, PremierTox billed

insurance companies for the tests with long delays. *Id.* Evidence at trial showed that timely results were material for the tests, but PremierTox said "nothing about the date the samples had been ordered or collected." *Id.* at 747–49. Further, the insurance company would not have paid for the tests if it had known about the delay. *Id.* at 749. A jury convicted defendants of "seventeen health care fraud charges." *Id.* at 748.

On appeal, the defendants challenged the weight of evidence. *Id.* The Sixth Circuit said that the case "comes down to the meaning of 'defraud' and whether the defendants satisfied it." *Id.* at 748. The issue was whether the defendants could be found guilty by not informing the insurance companies of the delays. *Id.* The Sixth Circuit ruled that a "knowing concealment of material facts" are "omissions of material fact . . . . " *Id.* The court then showed that material omissions justify fraud under other statues, including mail fraud, wire fraud, and bank fraud. *Id.* While *Bertram* also cites *Escobar*, it only cites to it to say that the false or fraudulent claims under False Claims Act include "'half-truths—representations that state the truth only so far as it goes, while omitting critical qualifying information,' all of which 'can be actionable misrepresentations.'" *Id.* at 748 (6th Cir. 2018) (quoting *Escobar*, 579 U.S. at 188). Relying on this citation, Defendant Bolos overstates the *Bertram* court's reliance on *Escobar.*

Even assuming Defendant's first two premises are correct, sufficient evidence at trial could lead a reasonable fact finder to determine that the misrepresentations and omissions made to PBMs were material and the evidence does not preponderate against the verdict. In his motion, Defendant makes the conclusory statement, "Neither Synergy nor Precision omitted material facts when submitting the individual claims for prescriptions." [Doc. 702, PageID 8560]. But the evidence listed above contradicts that statement. Representatives from the PBMs discussed at length the types of facts that were material to them under the PBM contracts and claims, and evidence at trial

established that Defendant Bolos and his co-conspirators made those misrepresentations. The PBM representatives even described certain misrepresentations that would lead to recoupment of already paid claims.

In his reply, Defendant attempts to cite another FCA case to, in effect, impeach trial witnesses on whether certain misrepresentations were material. [Doc. 732, PageID 11191]. The case cited by Defendant involves the use of a catchall-prescriber number when filling prescriptions. *United States ex rel. Spay v. CVS Caremark Corp.*, 875 F.3d 746, 750 (3d Cir. 2017). The catchall-prescriber number was used when a provided prescriber number did not work in the computer system. *Id.* That case has little resemblance to this case and does not establish as a matter of law that the misrepresentations in this case were immaterial to the PBMs.

2. HealthRight Doctors' Failure to Form a Physician-Patient Relationship

Like Defendant's implied false certification theory, this argument falls flat. Defendant argues that he cannot be responsible for HealthRight's failure to ensure that its doctors had physician-patient relationships with clients. [Doc. 702, PageID 8561]. Even if true, sufficient evidence at trial showed that Defendant Bolos and co-conspirators knew that the doctors did not form a physician-patient relationship, did not speak to patients, drafted attestations for responding to audits, and knew about altering attestations for the express purpose of ensuring that they would not raise "red flags." While he may not have had an affirmative duty to ensure a physician-patient relationship, Defendant cites no case law establishing that, absent an affirmative duty, he and his co-conspirators could make material misrepresentations and omissions.

3. Absence of Regulatory Compliance Certifications

In Defendant's next argument, he again relies on an FCA case involving implied false certification. [Doc. 702, PageID 8563]. Defendant argues "the FCA and therefore fraud statutes

related to health care fraud do not punish all statutory and regulatory violations." [*Id.* at PageID 8566]. He goes on to say, "Dr. Bolos did not make a material misrepresentation in the submission of a claim, nor did he conspire to do so." [*Id.*]. Defendant's first point is inapposite. Whether health care fraud punishes "all statutory and regulatory violations" is of no consequence here; the jury was not charged that it could find Defendant guilty if it found that he violated *any* statute or regulation. Further, adequate evidence was in the record so that a reasonable factfinder could determine that Defendant Bolos made material misrepresentations and conspired to do so, and the evidence does not preponderate heavily against the verdict.

In his reply, Defendant cites *Cleveland v. United States*, 531 U.S. 12 (2000), to argue that he cannot be guilty of fraud in regard to obtaining a pharmacy license. [Doc. 732, PageID 1194]. Again, this is not related to the United States' theory of the case or evidence at trial. While Defendant is correct, the mail fraud statute "does not reach fraud in obtaining a state or municipal license . . . , for such a license is not 'property' in the government regulator's hands[,]" *Cleveland*, 531 U.S. at 20, Defendant's convictions do not rest on simply obtaining the pharmacy license. Instead, as presented to the jury, Defendant "made and knew of false statements made to the Tennessee Board of Pharmacy, and other state boards of pharmacy, to obtain state pharmacy licenses, all while knowing that false statements made to state pharmacy boards was material to the PBMs." And evidence at trial indicated that the false statements made to obtain licenses were material to the PBMs. Defendant was found guilty of defrauding the PBMs, not the State of Tennessee.

4. Honest Services Fraud

Next, Defendant Bolos argues that he cannot be guilty of honest services fraud because the allegations did not involve a kickback, did not involve a bribe, and essentially only involved a

breach of contract. [Doc. 702, PageID 8566]. Honest services fraud is a particular type of fraud, and the United States Code specifically provides that it is a type of "scheme or artifice to defraud." 18 U.S.C. § 1346; *Skilling v. United States*, 561 U.S. 358, 400 (2010). In an honest services fraud scheme, an offender profits, but the defrauded party has no loss. *Skilling*, 561 U.S. at 400. Instead, a third-party enriched the offender. *Id.* "For example, if a city mayor (the offender) accepted a bribe from a third party in exchange for awarding that party a city contract, yet the contract terms were the same as any that could have been negotiated at arm's length, the city (the betrayed party) would suffer no tangible loss." *Id.*

Defendant Bolos says that "[h]e is charged not with swindling a third party out of money as is done in traditional fraud schemes, rather he is charged with failing to provide the PBM honest services by failing to disclose the alleged statutory and regulatory violations indicated in the FSI." [Doc. 702, PageID 8567]. But that statement is at odds with the FSI, evidence at trial, and the jury verdict. Defendant Bolos was neither charged nor convicted of honest services fraud. [*See* Verdict Form, Doc. 663; FSI, Doc. 278].

5. Personal Services Safe Harbor and Intent to Violate the Law

Next, Defendant argues that a safe harbor regulation, 42 C.F.R. § 1001.952(d), should apply in this case. [Doc. 702, PageID 8571]. This regulation pertains to Section 1128B(b) of the Social Security Act, also known as the Anti-Kickback Statute. 42 C.F.R. § 1000.10; *see Jones-McNamara v. Holzer Health Sys.*, 630 F. App'x 394, 395, 400 (6th Cir. 2015). Defendant was neither charged nor convicted under the Anti-Kickback Statute, and Defendant has not shown that the safe harbor regulation found at 42 C.F.R. § 1001.952(d), applies to conspiracy to commit health care fraud, mail fraud, or felony misbranding.

Defendant goes so far as to say that a failure to rule in his favor on this argument would be entrapment by estoppel. [Doc. 702, PageID 8579]. "The doctrine of entrapment by estoppel forbids prosecution of conduct which has been sanctioned by the government." *United States v. Neufeld*, 908 F. Supp. 491, 498 (S.D. Ohio 1995). The entrapment by estoppel defense is a jury question. *Id.* (citing *United States v. Pennsylvania Indus. Chemical Corp.*, 411 U.S. 655, 673 (1973)). The defense has four elements:

> (1) the government had announced that the charged conduct was legal;
> (2) the defendant relied on the government announcement;
> (3) the defendant's reliance was reasonable; and
> (4) given the defendant's reliance, the prosecution would be unfair.

Id.

Defendant did not raise this defense at trial and did not submit it as a question to the jury. Further, Defendant's argument that 42 C.F.R. § 1001.952(d) establishes an entrapment by estoppel is unpersuasive. The safe harbor regulation has no applicability to this case and cannot, on its own, satisfy the elements of entrapment by estoppel.

Also in this argument, Defendant contends that he did not intend to violate the law and no evidence at trial satisfies this heightened *mens rea* requirement. [Doc. 702, PageID 8577]. This argument is inapplicable as an intent to violate the law was not an element of any of his convictions.

6. Failure to Collect Co-Payments and 42 C.F.R. § 1001.952

Defendant says that a waiver of co-pays is not illegal if reasonable collection attempts are made. [Doc. 702, PageID 8571]. Defendant also argues that reasonable collection attempts were made. [*Id.*]. His authority for this proposition is 42 C.F.R. § 1001.952. This regulation, again, pertains to the Anti-Kickback Statute. 42 C.F.R. § 1000.10. [*Id.* at PageID 8571–72]. Defendant's cited regulation and the subsection he relies on states, in part, "The following payment practices

shall not be treated as a criminal offense under section 1128B of the [Society Security Act] . . . . " Defendant's practices and those of his co-conspirators were not treated as a criminal offense under the Anti-Kickback Statute, and the regulation does not apply to his case.

7. Lack of Medical Necessity

Next, Defendant makes four separate arguments about evidence regarding medical necessity and physician-patient relationships. He argues that his convictions should be overturned because (1) "the Government failed to support its claim that the prescriptions lacked medical necessity" and (2) the Government failed to support its claim "that a lack of medical necessity for a prescription falls on the pharmacist or pharmacy." [Doc. 702, PageID 8581]. Then, he goes on to say that (3) "Synergy did not falsely certify that HealthRight created a valid physician-patient relationship" and (4) "the Government failed to call an expert witness to establish the lack of a physician-patient relationship, and this is not a question for a lay witness." [*Id.*]. None of the arguments is persuasive.

Defendants first and second points have no bearing on the case. Neither the FSI nor the jury charge use the terms "medical necessity" or "medically necessary" with one exception. The FSI uses the term "medically necessary" when quoting a doctor-attestation. [Doc. 278, PageID 4061]. Considering the medical necessity of the products was not challenged, his points are meritless.

Third, Defendant argues that Synergy and Precision did not certify to any PBMs that physician-patient relationships were formed. The Court has already explained that this is not a false certification case under the FCA, explained that evidence in the record supports a finding that material representations and omissions were made, and the Court sees no need to address the argument further.

Fourth, without an expert, was the evidence sufficient for a conviction? Defendant says, "No." [Doc. 702, PageID 8581]. Citing to cases requiring expert witnesses on medical standards of care and medical purposes, Defendant argues that the Government needed an expert. [*Id.* at PageID 8581–82]. While Defendant shows that an expert is needed in some cases involving medical care, Defendant does not explain why the evidence was insufficient here.

Additionally, when citing a magistrate judge's order in this case, Defendant incorrectly states that the Government could not call Dr. Stephan Thomas as an expert witness to opine on physician-patient relationships. [*Id.* at PageID 8583]. That is untrue. This Court vacated the magistrate judge's order, in part, and deferred its ruling on whether Dr. Thomas could testify regarding the physician-patient relationship in the pain management setting until trial. [Doc. 511, PageID 6523]. Then, the Government did not call Dr. Thomas.

The Government says that the evidence was sufficient without an expert. The Government argues that the overwhelming evidence at trial showed that Defendant knew that there was a lack of a physician-patient relationship and knew that the prescriptions were issued anyway. [Doc. 726, PageID 11166].

The Government is correct. The record contains sufficient evidence that Defendant knew that the prescriptions were issued without a physician-patient relationship, and this was material to the PBMs. The evidence at trial could support a finding that Defendant knew that the patients and doctors had no relationship at all, never spoke to each other, patients did not know why they were getting prescriptions in the mail or who the doctor was, doctors did not know which prescriptions were actually sent to patients, and more. A reasonable jury could, based on those facts, determine that Defendant knew that a physician-patient relationship did not exist.

Further, Defendant's argument that an expert is needed to discuss the medical standard is unavailing in light of the evidence. Rule 702 of the Federal Rules of Evidence permits expert testimony when it "will help the trier of fact to understand the evidence or to determine a fact in issue . . . . " Fed. R. Evid. 702(a). It is unclear to the Court how an expert would assist the trier of fact in this case as evidence in the record supported a finding that Defendant Bolos knew that prescriptions were written without a physician-patient relationship. Additionally, the physician himself who wrote the prescriptions admitted that he did not have a physician-patient relationship under cross-examination.

In his reply brief, Defendant cites Tenn. Comp. R. & Regs. 0880–02–.16 to argue that a physician-patient relationship was formed. Citing this regulation, Defendant says, "A physician-patient relationship is established when 'a physician serves a patient's medical needs whether or not there has been an encounter in person between the physician and patient.'" [Doc. 732, PageID 11198–99]. But the regulation cited by Defendant clearly states in its heading, "Unless specifically set out in this rule, this rule is not intended to and does not supersede any pre-existing federal or state statutes or rules and is not meant to alter or amend the applicable standard of care in any particular field of medicine or to amend any requirement for the establishment of a physician-patient relationship." Tenn. Comp. R. & Regs. 0880–02–.16. On its own terms, the regulation cited by Defendant does not "amend any requirement for the establishment of a physician-patient relationship." *Id.* Therefore, the regulation does not assist his argument.

V. Conclusion

For the reasons stated above, Defendant Bolos's Motion for Judgment of Acquittal Pursuant to Rule 29 or in the Alternative Motion for New Trial Pursuant to Rule 33, [Doc. 702],

is DENIED. Based on the evidence at trial, Defendant is not entitled to an acquittal or a new trial. Additionally, no legal error has occurred that would entitle Defendant to an acquittal or a new trial.

So ordered.

ENTER:

s/J. RONNIE GREER
UNITED STATES DISTRICT JUDGE